UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

Antimicrobials Division (AD)

May, 2013.

DP BARCODE:		411473.
MRID:		48992101 & 48992102.
SUBJECT:		**Antimicrobial Corning Gorilla Glass.**
REG. NO. OR FILE SYMBOL:		89661-R.
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [X]	OR	End - Use Product [X]
INGREDIENT (PC Code)		Silver Oxide (072500)

CAS Number:	14701-21-4.
TEST LAB:	Technology Sciences Group Inc.
SUBMITTER:	Corning, Inc.
GUIDELINE:	830 tables A & B.
COMMODITIES:	Formulation
REVIEWER:	Salvador Rodriguez.
ORGANIZATION:	AD.
APPROVER:	Karen P. Hicks.
APPROVED DATE:	

05/03/13

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

May, 2013.

MEMORANDUM

Subject:	Product Chemistry Review for EPA Reg # 89661-R.
Product name:	**Antimicrobial Corning Gorilla Glass.**
DP#:	411473.
From:	Salvador Rodriguez, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P)
Thru:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobials Division (7510P)
To:	Marshall Swindell / Martha Terry. PM Team 33 Antimicrobials Division (7510P)
APPLICANT:	Wego Chemical & Mineral Corp.
Action code:	A540.
Due date:	05/06/2013.

Product Formulation
Active Ingredient

	% by wt
Silver.....	0.2

BACKGROUND:

On behalf of the registrant, Corning Incorporated, the consultant, Technology Sciences Group Inc., has submitted a Confidential Statement of Formula (CSF), for the basic formulation and the OPPTS Guideline Series 830 Groups "A & B", to support the registration for the antimicrobial, integrated, non-food and end-use product **Antimicrobial Corning Gorilla Glass.** The product chemistry reviewer has reviewed the following documents:

- Transmittal letter, dated 11/13/12. MRID#: 48992100.
- Application for pesticide, dated 11/13/12.
- Confidential Statement of Formula, dated 11/13/12, for the basic formulation.
- Draft label, dated 11/13/12.
- OPPTS 830 Guideline tables A & B. MRID #'s: 48992101 & 48992102.
- Data matrix, dated 11/13/12.

FINDINGS:

1. The CSF, dated 05/02/13, for the basic formulation is revised.

2. The CSF and the label have the same nominal concentration for the active ingredient (AI).

3. All certified limits do not meet the EPA standard certified limits. In addition, the active ingredient statement suggested that the certified limits are outside of the EPA Standard Certified Limits due to dependency of silver percentage content on the glass thicknesses. The registrant has submitted a justification letter for the use of wider certified limits, dated 05/01/13.

4. The OPPTS Guidelines Series 830 Groups "A & B" product chemistry data requirements applicable to end-use products have not been met. The data provided for this group "A & B", are not based on the silver oxide as active ingredient, it is based on the silver nitrate as an active ingredient (AI). MRID #: 48992101 & 4899210

7. The registrant indicated that these five pilot-scale batches for the product **Antimicrobial Corning Gorilla Glass** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed in duplicate and the average of the two readings was used to express the weight % active ingredient (AI) in each sample. The results are the following:

Glass #	Silver (%w)
3	0.03
15	0.05
1	0.24
14	0.70
13	0.90

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the proposed CSF for the basic formulation, dated 05/02/13, for the EPARN 89661-R, and the OPPTS Guidelines Group A and OPPTS Guidelines Group B to be acceptable. The results of the five batch analysis OPPTS 830.1700 are not within the EPA standards certified limits. The registrant submitted an updated CSF to show wider certified limits for the AI. The registrant also submitted a justification letter for the wider certified limits for the AI. These wider certified limits are acceptable.

The formulation shows two components, silver and the glass. The silver comes in a solution in which at high temperature the silver is removed from the molecule. The silver then is attached to the glass. The glass is exposed in the first ion exchange to prepare the glass surface. The second ion exchange the silver becomes bonded to the glass surface creating a film throughout the glass surface. The enforcement analytical method is based on grinding the entire glass. Therefore, the AI will not be homogeneous and the assay may vary.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]

c. Physical state of product: *Solid.*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Silver	0.2	0.18	0.22

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

II **PRODUCT LABEL**

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [X]

Note: The Storage stability study and the corrosion characteristics study should be submitted upon completion.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	48992101
830.1600 Description of Materials	A	48992101
830.1620 Production Process[2]	A	48992101
830.1650 Formulation Process[3]	A	48992101
830.1670 Formation of Impurities[4]	N/A	48992101
830.1700 Preliminary Analysis[5]	U	48992101
	A The registrant updated the information. MRID number in progress.	
830.1750 Certified Limits[6]	A	48992101
830.1800 Enforcement Analytical Method[7]	N	48992101
	A The registrant updated the information. MRID number in progress.	
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Colorless.	48992102
830.6303 Physical State	A	Solid	48992102
830.6304 Odor	A	Odorless.	48992102
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Contact with hydrofluoric acid must be avoided.	48992102
830.6315 Flammability/ Flame Extension	A	All of its constituents are inorganic, and none is pyrophoric.	48992102
830.6316 Explodability	A	The product does not contain organically-bonded nitro groups.	48992102
830.6317 Storage Stability	N	The storage stability study should be submitted upon completion.	
830.6319 Miscibility[1]	A	This product is to be diluted in glass.	48992102
830.6320 Corrosion Characteristics	N	The corrosion characteristics study should be submitted upon completion.	
830.6321 Dielectric Breakdown Voltage	NR	The product is not a liquid.	48992102
830.7000 pH[2]	A	The product is not a liquid.	48992102
830.7050 UV/Visible Absorption	NR	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The product is not a liquid.	48992102
830.7200 Melting Point/Melting Range	NR	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	The product is not a liquid.	48992102
830.7300 Density/Relative Density/Bulk Density	N	2.45 g/mL	48992102
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	